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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,947

09/09/2003

Sean C. Semple

INEX.P-003-3

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08/08/2006

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,947	SEMPLE ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/8/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-91 and 93-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-91 and 93-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

An amendment of 5/8/06 amended claims 85-91, 93-101, 105, 107 and 108, added new claims 109 and 110, and canceled claim 92.

Claims examined on the merits are 85-91 and 93-110, which are all
5 claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 103 and 104 are rejected under 35 U.S.C. 112, first
10 paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15 Support is not found in the specification for the nucleic acid-lipid particle not being substantially degraded at a temperature and time as required by claims 103 and 104. Example 10 disclosing that free phosphorothioate oligodeoxynucleotide shows significant breakdown in serum within 30 minutes is inadequate support. A time of 20
20 minutes is not found in the specification.

Response to Arguments

It is granted as urged by applicants that the claimed subject matter need not be described in the specification literally. However, when not described literally, the specification must provide clear
25 support for the claimed subject matter. Example 10 disclosing that

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free phosphorothioate oligodeoxynucleotide shows significant breakdown in serum within 30 minutes, and the encapsulated nucleic acid not degrading even after 24 hours is inadequate support for selecting 30 minutes as a time less than 24 hours which degradation of the encapsulated nucleic acid does not occur. Selecting 30 minutes for degradation not occurring permits degradation after 30 minutes. This changes the original description in the specification. A time of 20 minutes is not found in the specification as a time for degradation not occurring. For the same type of reasons set forth above in regard to 30 minutes, there is no basis for selecting 20 minutes as a time degradation does not occur, and after which degradation can occur.

Double Patenting

Claims 85-91, 93, 97-106 and 108-110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,858,225 B2 in view of Collins and Cullis et al and Wheeler et al (WO) for reasons set forth in the previous office action of 11/7/05.

Double Patenting

Claims 94-96 and 107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,858,225 B2 in view of the references as applied to claims 85-91, 93, 97-106 and 108-110 above, and further in view of Wheeler et al ('410) and Unger ('276).

It would have been obvious to use DODMA as the amino-lipid of the patent claims as suggested by Wheeler et al ('410) using DODMA (col

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51, line 64) as a component of a nucleic acid-lipid particle similar to that of the patent claims. When providing a neutral lipid in the nucleic acid-lipid particle of the patent claims as set forth above, it would have been obvious to use DSPC as the neutral lipid as suggested by Unger disclosing using DSPC in preparing a lipid vesicle.

Response to Arguments

Applicants indicate that a terminal disclaimer will be filed when the claims are otherwise allowable.

Double Patenting

10 Claims 85-91, 93, 94, 97-106 and 108-110 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6,287,591 B1 in view of Collins and Cullis et al for reasons set forth in the previous office action.

15 ***Double Patenting***

Claims 95, 96 and 107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6,287,591 B1 in view of the references as applied to claims 85-91, 93, 94, 97-106 and 108-110 above, and in further view of Wheeler et al ('410) for reasons in the previous office action.

Response to Arguments

Contrary to applicants' argument, Wheeler et al does not require DODMA-AN. See claim 4, line 6, where DODMA is the cationic lipid.

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Applicants indicate that a terminal will be filed when the claims are otherwise allowable.

Conclusion

The claims are free of the prior art.

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

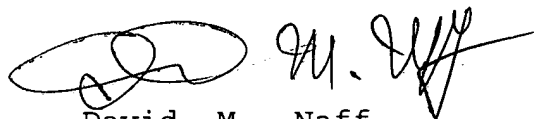
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date
10 of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
15 however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be
20 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

8/5/09